IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):

Zoltan Kiss

Appln. No.:

10/582,391

Filing Date:

June 9, 2006

Title:

METHOD FOR IMPROVING INSULIN SENSITIVITY BY

ADMINISTERING AN INHIBITOR

OF ANTITRYPSIN

Examiner:

Group Art Unit:

Confirmation No.:

Customer No.:

25764

Docket No.:

59496 - 336756

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

I CERTIFY THAT THIS CORRESPONDENCE IS BEING ELECTRONICALLY TRANSMITTED TO THE U.S. PATENT AND TRADEMARK OFFICE ON DECEMBER 94,2006.

INFORMATION DISCLOSURE STATEMENT

In compliance with the duty imposed by 37 C.F.R. 1.56, and in accordance with C.F.R. sections 1.97 et seq., the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Consideration of each of the documents listed on the attached SB/08 form(s) is respectfully requested. The filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is construed to be, prior art or material to the patentability of the present application.

This Information Disclosure Statement is being filed before the receipt of an Office Action on the merits. No fee is believed to be necessary. However, should any fee be required, the Commissioner is authorized to charge our Deposit Account No. 06-0029 and is requested to notify us of the same.

Respectfully submitted,

FAEGRE & BENSON LLP

By:

Tanya S. D'Souza, Reg. No. 56,948 612/766-7835 Customer No.: 25764

Dated: December 39, 2006

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	IFORMATION DISCLOSURE			Application Number	10/582,391
INFC	RMATION	DIS	CLOSURE	Filing Date	December 9, 2004
STA	TEMENT B	ΥΑ	PPLICANT	First Named Inventor	Zoltan Kiss
				Art Unit	
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Sheet	1	of	4	Attorney Docket Number	59496 - 336756

	·······	,	U.S. PATENT I		
Examiner Initials *	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
		Number - Kind Code ² (<i>if known</i>)			Figures Appear
		US- 5,593,971	01-14-1997	Tschollar et al.	
		US- 6,133,293	10-17-2000	Ikeda et al.	
		US- 6,174,859 B1	01-16-2001	Lezdey et al.	
	Ī	US- 6,515,117 B2	02-04-2003	Ellsworth et al.	
		US- 6,555,519 B2	04-29-2003	Washburn	
		US- 6,608,112 B1	08-19-2003	D'Armiento et al.	
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•	FOREIGN PATENT DOCUMENTS						
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages Or		
Initials*	No.1	Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>)	MM-DD-YYYY	Applicant of Cited Document	Relevant Figures Appear	T ⁶	
		1149-11114-11					

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Substitute	NFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	Complete if Known			
INFO	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	CL OCUBE	Application Number	10/582,391	
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) Sheet 2 of 4		Filing Date	July 14, 2006	
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	(Use as many she	ets as	necessary)	Examiner Name	
Sheet	2	of	4	Attorney Docket Number	59496 - 336756

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
		ZIMMET et al., "Global and societal implications of the diabetes epidemic," <i>Nature</i> 414 , pp. 782-787, 2001	
		SALTIEL et al., "Insulin signaling and the regulation of glucose and lipid metabolism," <i>Nature</i> 414 , pp. 799-806, 2001	
		BELL et al., "Diabetes mellitus and genetically programmed defects in β-cell function." <i>Nature</i> 414 , pp. 788-791 2001	
		MATHIS et al., "β-cell death during progression to diabetes." <i>Nature</i> 414 , pp. 792-798, 2001	
		SALTIEL, "New perspectives into the molecular pathogenesis and treatment of Type 2 diabetes," <i>Cell</i> 104 , pp. 517-529, 2001	
		MOLLER, "New drug targets for Type 2 diabetes and the metabolic syndrome," <i>Nature</i> 414 , pp. 821-827, 2001	
		BROWNLEE, "Biochemistry and molecular cell biology of diabetic complications," <i>Nature</i> 414, pp. 813-820, 2001	
		HO et al., "Antioxidants, NFkB activation, and diabetogenesis," <i>Proc. Soc. Exp. Biol. Med.</i> 222 , pp. 205-213, 1999	
		BODEN et al., "FFA cause hepatic insulin resistance by inhibiting suppression of glycogenolysis," Am. J. Physiol. Endocrinol. Metab. 283, pp. E-12-E19, 2001	
		YU et al., "Mechanism by which fatty acids inhibit insulin activation of insulin receptor substrate-1 (IRS-1)-associated phosphatidylinositol 3-kinase in Muscle," <i>J. Biol. Chem.</i> 277 , pp. 50230-50236, 2002	
		MAEDLER et al., "Distinct effects of saturated and monounsaturated fatty acids on β-cell turnover and function," <i>Diabetes</i> 50 , pp. 69-76, 2001	
		PRADHAN et al., "C-reactive protein, interleukin 6, and risk of developing Type 2 diabetes mellitus," <i>JAMA</i> , 286 , pp. 327-334, 2001	
		THOMPSON et al., "Insulin modulation of acute-phase protein production in a human hepatoma cell line," <i>Cytokine</i> 3 , pp. 619-626, 1991	
		CAMPOS et al., "Insulin is a prominent modulator of the cytokine-stimulated expression of acute-phase plasma protein genes," <i>Mol. Cell. Biol.</i> 12, 1789-1797, 1992	
		GANROT et al., "Serum concentration of α ₂ -macroglobulin, haptoglobin and α ₁ -antitrypsin in diabetes mellitus," <i>Acta Endocrinologica</i> 55 , pp. 537-544, 1967	

	 	
Examiner	Date	
Signature	Considered	

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	NFORMATION DISCLOSURE			Application Number	10/582,391
		-		Filing Date	July 14, 2006
STAT	STATEMENT BY APPLICANT			First Named Inventor	Zoltan Kiss
				Art Unit	
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Sheet	3	of	4	Attorney Docket Number	59496 - 336756

	T	NON PATENT LITERATURE DOCUMENTS	1
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Τ²
		MCMILLAN, "Increased levels of acute-phase serum proteins in diabetes," <i>Metabolism</i> 38 , pp. 1042-1046, 1989	
		SCHMIDT et al., "Markers of inflammation and prediction of diabetes mellitus in adults," <i>The Lancet</i> 353 , pp. 1649-1652, 1999	
		JANCIAUSKIENE, "Conformational properties of serine proteinase inhibitors (serpins) confer multiple pathophysiological roles," <i>Biochim. Biophys. Acta</i> 1535 , pp. 221-235, 2001	
		WEWERS et al., "Replacement therapy for alpha ₁ -antitrypsin deficiency associated with emphysema," N. Engl. J. Med. 316, pp. 1055-1062, 1987	
		PERRAUD et al., "Proliferation of rat astrocytes, but not of oligodendrocytes, is stimulated in vitro by protease inhibitors," <i>Int. J. Devl. Neuroscience</i> 6, pp. 261-266, 1988	
		SHE et al., "α ₁ -antitrypsin can increase insulin-induced mitogenesis in various fibroblast and epithelial cell lines," <i>FEBS Lett.</i> 473 , pp. 33-36, 2000	
		DABBAGH et al., "Alpha-1-antitrypsin stimulates fibroblast proliferation and procollagen production and activates classical MAP kinase signaling pathways," <i>J. Cell. Physiol.</i> 186 , pp. 73-81, 2001	
		GRAZIADEI et al., "The acute phase protein α ₁ -antitrypsin inhibits growth and proliferation of human early erythroid progenitor cells (burst-forming units-erythroid) and of human erythroleukemic cells (K562) in vitro by interfering with transferring iron uptake," <i>Blood</i> 83, pp. 260-268, 1994	
		YAVELOW et al., "α ₁ -antitrypsin blocks the release of transforming growth factor-α from MCF-7 human breast cancer cells," <i>J. Clin. Endocrinol. Metab.</i> 82 , pp. 745-752, 1997	
		OZEKI et al., "α ₁ -antitrypsin and hepatic fibrosis," <i>Br. J. Exp. Path.</i> 70, pp. 143-152, 1989	
		GRAZIADEI, "Modulation of iron metabolism in monocytic THP-1 cells and cultured human monocytes by the acute-phase protein α ₁ -antitrypsin," <i>Exp. Hematol.</i> 26 , pp. 1053-1060, 1998	
		JANCIAUSKIENE et al., "An interaction between Gemfibrozil and alpha ₁ -antitrypsin," J. Internal Med. 236, pp. 357-360, 1994	
		JANCIAUSKENE et al., "The interaction of hydrophobic bile acids with the α ₁ -proteinase inhibitor," <i>FEBS Lett.</i> 343 , pp. 141-145, 1994	
		JANCIAUSKIENE et al., "In vitro complex formation between cholesterol and α ₁ - proteinase inhibitor," <i>FEBS Lett.</i> 316 , pp. 269-272, 1993	

Examiner	Date	
Signature	Considered	

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			CLOSURE	Filing Date	July 14, 2006
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				Art Unit	
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Sheet	4	of	4	Attorney Docket Number	59496 - 336756

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nitials *	No. ¹	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		YUAN et al., "Changes in composition and distribution of LDL subspecies in hypertriglyceridemic and hypercholesterolemic patients during gemfibrozil therapy," <i>Atherosclerosis</i> 110, pp. 1-11, 1994	
		SCHAEFER et al., "Effects of regular and extended-release gemfibrozil on plasma lipoproteins and apolipoproteins in hypercholesterolemic patients with decreased HDL cholesterol levels," <i>Atherosclerosis</i> 127, pp. 113-122, 1996	
		RUBINS et al., "Gemfibrozil for the secondary prevention of coronary heart disease in men with low levels of high-density lipoprotein cholesterol," <i>N. Engl. J. Med.</i> 341 , pp. 410-418, 1999	
		SCHULZE et al., "Evidence for the extent of insertion of the active site loop of intact α_1 proteinase inhibitor in β -Sheet A," <i>Biochemistry</i> 31, pp. 7560-7565, 1992	
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